Reply to Office Action of 04/25/2011

REMARKS/ARGUMENTS

In view of the following remarks, favorable reconsideration of the pending claims is requested.

Status of the Claims

Claims 1, 3-5, 7-12, 16-19, and 21-22 are pending.

Claim 11 has been amended to clarify the claimed invention. Applicant submits that the amendment to Claim 11 does not raise any new issues for consideration.

Rejections under 35 U.S.C. § 112

Claim 11 has been rejected under 35 U.S.C. § 112, second paragraph, as being indefinite because the term "before granulation" in Claim 1 allegedly does not have sufficient antecedent basis. Claim 11 has been amended to recite that the particles of dehydrated bacteria have an average size of between 80 and 150 µm prior to granulation.

Please note that the basis for this amendment of claim 11 may be found in the specification of the present application, see in particular paragraph [0029] of the US 2007/098847 application as published:

[0029] The average size of the particles of dehydrated bacteria (before their granulation) is preferably approximately between 80 and 150 μm . In this regard, the size of the particles of dehydrated bacteria can optionally be adjusted, for example, by milling according to the conventional techniques well known to those skilled in the art.

Rejections under 35 USC § 103(a)

Claims 1, 3-5, 7-12, 16-19, and 21-22 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over Santus (US 5,952,021 **R1**) in view of previously cited Rutherford et al. (US 5,292,657 **R2**).

As explained previously, the technical problem of the present invention is the preparation of a liquid aqueous food product containing viable probiotic microorganisms encapsulated in granules that are <u>not perceptible</u> in the mouth when drinking said liquid food product; more

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specifically, the purpose is thus to maintain said microorganisms viable in a low pH (4.5 or less) and highly aqueous (water content of at least 90%) environment.

This technical problem has been solved by the encapsulation of dried microorganisms with vegetable fats that are solid at ambient temperature in such a way that the granules of encapsulated microorganisms have an average size of less than 200 µm. The small granules size is crucial for purposes of distribution/dispersion stability in liquid food products and taste effect (to avoid perception of the granules when consuming the liquid food product).

Santus (US 5,952,021, **R1**) describes a method to protect bioactive compounds and microorganisms from inactivation in the gastric tract as well in the food.

In particular, **R1** describes the preparation of granules of microorganisms coated with a polymeric enteric coating; said coated granules having sizes ranging from 50 to 500 μ m and may be suspended in a liquid or semi-liquid food.

None of the coating material used in **R1** is chosen amongst fat, food waxes, fatty acids and oils.

Furthermore, R1 does not describe granules of coated microorganisms having a size of less than 200 μm .

As previously detailed, Rutherford et al. (US 5,292,657, **R2**) describes the preparation of freeze-dried microorganisms entrapped in a fatty acid matrix capable of maintaining bacterial activity in acidic environment; the entrapped freeze-dried microorganisms are obtained with very specific equipment.

R2 uses a very particular process (different from the method used for preparing granules according to the present invention) leading to the granules in which microorganisms are <u>mixed</u> and entrapped into the fatty acid matrix whereas particles of microorganisms of the present invention are coated with vegetable fat solid at ambient temperature.

R2 does not describe how to formulate said capsules in liquid food products; microspheres of R2 may only be mixed in a dry feed product.

First, the preparation of a stable dispersion of microspheres in a liquid food product (R1 only describes suspendable coating granules, Table 5 shows that said granules quickly sediment)

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and the **taste** of these microspheres are not problems that are addressed in **R1**; the teaching of **R1** is not relevant for the person skilled in the art.

Furthermore, the person skilled in the art would find no incentive to combine the teaching of **R2** and **R1** to address the problem of the present Patent Application:

- none of these references are relevant to address the problem of preparing an aqueous beverage with <u>imperceptible</u> granules of probiotics: the only purpose of **R1** is to find a convenient coating to protect granules from acidic conditions; and **R2** refers only to dry food products;
- the person skilled in the art who tries to prepare an aqueous beverage would not have considered the teaching of **R2** which concerns dry feed product;
- the process for preparing granules of **R2** is very specific, the obtained granules do necessarily have a gravity compatible with the gravity of the liquid food product cited in **R1**; the skilled would have had to overcome a technical prejudice to combine these two documents;
- as they are essentially composed of fat and they do not contain any starch, the granules of **R2** are very lipophilic (more than the granules of **R1**); as a consequence, a person skilled in the art would have been deterred from using such granules in water containing food product such as liquid food product cited in **R1**.

Further, the combination of **R1** and **R2**does not disclose or suggest the claimed invention. More specifically, even if one tries to combine the liquid food product described in **R1** with the granules of **R2**, the resulting liquid food product (i) is <u>not</u> an aqueous beverage with a <u>stable</u> <u>dispersion of granules</u>; (ii) does not contain granules of encapsulated microorganisms having an average size <u>of less than 200 µm</u> and (ii) does not contain granules with <u>a core composed of dehydrated lactic acid bacteria and a coating layer of vegetable fat</u>. Thus, the combination of **R1** and **R2** fails to disclose or suggest the claimed invention and for this additional reason, the Examiner has failed to establish a prima facie case of obviousness.

Even by combining the knowledge of **R1** and **R2**, a person skilled in the art would not have prepared a liquid food product containing granules of probiotic microorganismsthat are not perceptible in the mouth.

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Compared to prior art, the combination of technical features of the food product according to claim 1 leads surprisingly to:

- a very good viability of the microorganisms as shown in the experimental examples of the present Application;
- a very good dispersion and physical stability of the lipophilic granules in the essentially aqueous food product; and
- a very good organoleptic quality of the liquid food product: granules are not perceptible in the mouth when mixed with a liquid food product (feeling of grains of sand on the palate).

Given the above, the liquid food product of claims 1 is not obvious in view of the teaching of R1 and R2.

In view of the foregoing amendments and remarks, Applicant respectfully submits that the rejections under 35 U.S.C. § 103(a) and 112 have been overcome and that the pending claims are in condition for allowance.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any required fee (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,

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